MAR 1 3 2012

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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NuVasive, Incorporated
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Date Prepared: September 1, 2011

B. Device Name

Trade or Proprietary Name:	*NuVasive CoRoent® No-Profile System*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Device Class:	Class II
Classification:	21 CRF §888.3080
Product Code:	MAX, OVD

C. Predicate Devices

The subject *NuVasive CoRoent No-Profile System* is substantially equivalent to the following device:

510(k) Number	Product Name
K100043	NuVasive CoRoent XLR Standalone System
K102090	SpineSmith Cynch Spinal System – Visualif Interbody Fusion Implant System
K041617, K073109	SurgiCraft STALIF™ TT Intervertebral Body Fusion System
K091301	Life Spine® Stand-Alone Spacer System (Dyna-Link®)
K082252	Globus Medical Independence® Spacer

D. Device Description

The *NuVasive CoRoent No-Profile Standalone System* is manufactured from PEEK-Optima LT1, titanium alloy, and Nitinol SE508 alloy. The implants are available in a variety of sizes to suite the individual pathology and anatomical conditions of the patient. The *CoRoent No-Profile Standalone System* is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

E. Intended Use

The *CoRoent No-Profile System* is a standalone system indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The *CoRoent No-Profile System* is intended for use with autograft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the *CoRoent No-Profile System*.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent No-Profile System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *CoRoent No-Profile System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static & Dynamic Axial Compression testing per ASTM F2077-03
- Static & Dynamic Torsion testing per ASTM F2077-03
- Expulsion testing per Draft standard, work item Z8423Z
- Subsidence testing per ASTM F2267-04
- Wear Debris per ASTM F2077 & ASTM F17877
- Axial Screw Pullout per ASTM F543
- Screw Push-out Testing
- Screw Push-through Testing
- Static Separation Testing

The results of these studies, as well as the descriptive information presented, demonstrates that the subject *CoRoent No-Profile System* is substantially equivalent to the performance of the predicate devices, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *CoRoent No-Profile System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Inc.
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

MAR 1 3 2012

Re: K112561
Trade/Device Name: NuVasive CoRoent No-Profile System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson MD Chief

Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112561

Device Name: NuVasive® CoRoent® No-Profile System

Indications For Use:

The CoRoent No-Profile System is a standalone system indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The CoRoent No-Profile System is intended for use with autograft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the CoRoent No-Profile System.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112561